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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

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THE PROCTER & GAMBLE COMPANY
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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,351	JANDACEK ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-78* is/are pending in the application.

4a) Of the above claim(s) *37-70 and 72-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-36 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/02/08 has been entered.

The response filed on **7/02/08** presents remarks and arguments to the office action mailed on **2/22/08**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1, 3-36 and 71 are pending in this office action.

Claims 37-70 and 72-78 are withdrawn as non-elected species.

Maintained Claim Rejections - 35 USC § 112

Claims 1, 3-36 and 71 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", "at least about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "at least about".

Applicant argues that: It is respectfully submitted that the term "about" as used in the present claims does not render the claims indefinite under 35 USC §112, Second Paragraph. As stated in the MPEP under 2173.05(b) A, the term "about" has been held to be "clear, but flexible" citing *Ex parte Eastwood,* 163 USPQ 316 (Bd. App. 1968) *and W.L. Gore & Associates,Inc. v. Garlock, Inc.,* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). In *Gore,* the Court held that the use of "about" in defining stretching of a plastic at a rate "exceeding about 10% per second" is definite, since infringement could be assessed through the use of a stopwatch or timing device. By the same token,

infringement of the present claimed method could be assessed by the use of a timing device if the duration of the treatment period were the issue.

Examiners response: Applicant's argument emphasis on the term "about" which is not what is rejected. The term "about" permits some tolerance and that is not what is rejected. This is not the case here. In the instant case the term "at least about" is indefinite because "nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term "from about and at least about". That is the case here, nothing in the instant specification, prosecution history, or prior art provides any indication as to what range would be covered by the claimed term "at least about" or "from about".

Applicant's arguments have been fully considered but they are not persuasive. See reasons above.

Maintained Claim Rejections - 35 USC § 103

I. Claims 1, 3-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

II. Claims 13-24 remain rejected under 35 U.S.C. 103(a)as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

Applicant argues, that the cited reference de Smidt teaches a pharmaceutical composition comprising glyceride with a melting point of 37°C and a lipase inhibitor, but do not teach the stiffening agent and neither does Maeder et al. disclose a stiffening

agent. Further, Applicant argues that Maeder teaches away from the claim invention in that The Examiner states that Maeder et al. discloses a pharmaceutically active compound with a melting point > and or = to 37°C and fatty acid droplets below body temperature 37°C, See Column 3, line 25. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. W.L. Gore & Assocs. v. Garlock, Inc., 220 USPQ

Examiners response: taking the de Smidt reference for instant that the claims recite a pharmaceutical composition comprising at least one fatty acid ester of a polyol and a lipase inhibitor, see col. 1, lines 46-48 having a melting point of 37. Interpreted in Examiners view point the prior art of de Smidt would be capable of modification or substitution of the glyceride/glycerol and its sugar alcohol to a fatty acid. As to the allege statement that the art does not teach a stiffening agent , is found not persuasive, because per definition from the claims the agent must have a melting point of 33 and above, the de Smidt composition teaches that the melting point of the composition is above 33. See col. 2, lines 45-49. Also the reference teaches specifically that the fatty acids moieties have twelve or more carbon atoms which are interpreted to be up to 24 carbon atoms. See col. 3, lines 58+.

Examiner added Maeder as a secondary reference because of its teaching of specific fatty acids (such as oleic, stearate myristic, behenic acids and their pharmaceutically acceptable salts etc, see col. 5, lines 40-45) which can be employed

by substituting glyceride/glycerol and its sugar alcohol of de Smidt reference with the fatty acids of Maeder. Further the Maeder reference teaches that the composition has a melting point greater than 33. See Abstract. Applicant's allegation that Maeder deviates from the teaching in that the reference discloses a pharmaceutically active compound with a melting point > and or = to 37°C and fatty acid droplets below body temperature 37°C, See Column 3, line 25.. This is found not persuasive because less than 37 is still greater than 33 as required by the instant claims. Also it is noted that that the claims are to a composition and not to what occurs after the composition is ingested.

Based on the teachings from the prior art, one of ordinary skill in the art would have been motivated to formulate a composition substitute the fatty esters of de Smidt with that of Maeder and expect success in doing so because the teachings are directly related to the claim invention in that they comprise fatty acid and a lipase inhibitor wherein the inhibitors employed in the prior art is the same as Applicant's and the fatty acids is the same or can be substituted to give the same result. The only difference is that the prior art fails to teach the specific ratio of 5:1, however, the reference makes it obvious for such a range to be employed. As taught by de Smidt, the stiffening agent may be in the range of 0.5-90% and the enzyme in the range of 1-50%. If one takes 50% of the stiffening agent and 10% of the enzyme then the ratio is 1:5. As stated in the prior office action the determination of a ratio having the optimum index is well within the purview of the skilled artisan. It is the Examiners view that once the concept is known or available, one of ordinary skill in the art would be motivated to find the

optimum working range. Also it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). Also, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *See In re Keller,* 642 F 2d 413, 208 USPQ 871 (CCPA 1981)*; In re Merck &Co.,* 800 F.2d 1091, 231 USPQ (Fed. Cir. 1986).

Careful Consideration has been given and found not persuasive.

The above response is related to **claims 25-30** as the same arguments were made with the emphasis that de Smidt discloses a combination of fatty acid esters of polyols with a lipase inhibitor.

Applicant is right in stating that de Smidt discloses a combination of fatty acid esters of polyols with a lipase inhibitor, however, Maeder, teaches broadly that the composition comprises of fatty acid or fatty acid salts, this general teaching would motivate one to employ any fatty acid and therefore one of ordinary skill in the art would be motivated to substitute the polyol fatty acid with that of Maeder and expect success in doing so because both sets of fatty acids in the prior art has a melting point above 37 degrees Centigrade. Therefore the substitution of de Smidt polyol to that of Maeder would have been obvious. Further, Maeder teaches the same compound as claimed by Applicant, unless there is a showing that the composition of Maeder (having the same fatty acid as that of Applicant's) would exhibit different properties. It is the examiners position that the properties behenic and or oleic fatty acids would be the same.

The rejection of claims 31-36 and 71 has been considered and Hird is removed from the rejection, a new rejection is set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-36 and 71 are rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 or Maeder et al. US 6,730,319 B2 in view of Hug et al. US 6,358,522 and further in view of Park et al. US 5,750,585

With regards to claim 31 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and a lipase inhibitor (see col. 1 lines 46+) as in claim 35 and 71, wherein the stiffening agent is at least 5% (see col. 4, lines 38-65) as in claim 33.

As to claim 32, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 35 and 36. The reference fails to teach the ratio as 5:1 stiffening agent to lipase inhibitor and the specific stiffening agent calcium stearate.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor (tetrahydrolipstatin) (see col. 4, lines 48-60), a fatty acid and salts thereof (col. 4, lines 1-9) having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claim 31(ii), 32 and 34-36. The reference also teaches with regards to instant claim 33, the reference teaches a weight by weight composition wherein it is assumed that the stiffening agent is at least greater than 0.1 % as claimed because the reference teaches the composition comprises 0.5 mg-2 mg per 1 mg of lipase inhibitor. Maeder teaches

the fatty acids may be a stearic acid wherein the salts of this fatty acid can be calcium. Thus calcium stearate fatty acid may be obtained and therefore obvious. See col. 5, lines 16-45.

Hug et al. teach a pharmaceutical compositions containing an inhibitor of gastrointestinal lipases, one (or more) additive(s) of the group consisting of substantially non-digestible food grade thickeners and emulsifiers, and excipients (see abstract) wherein the compositions are useful for inhibiting anal oil leakage (see col. 1, lines 56-57).

Park et al. teach open-celled foam compositions and methods of orally administering said forms compositions for the treatment of obesity (see column 3, lines 15-25 and column 15, lines 16-32).

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

Further one of skill would be motivated to combine the teachings of de Smidt et al. taken with Maeder et al in view of Hug et al. for the absorption of oil as taught by Hug et al. in the treatment of anal oil leakage. Also, one of ordinary skill in the art would be motivated to combine the cited art add a non-digestive, non-absorbable, open celled polymeric foam because this composition can be used to treat anal leakage as taught by Hug et al. (see col. 1, lines 58-66) and Park et al. because these open celled forms inhibit digestion by the gastric fluid.

Regarding the ratio, even though the combined references do not teach the ratio as claimed, however, suggestions taught by both de Smidt and Maeder. de Smidt teaches the stiffening agent is at least 5%; see col. 4, lines 38-65 and Maeder teaches a w/w composition wherein the weight is 2:1 if 2 mg of the stiffening agent and 1 mg of the fatty acid is employed. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). Thus optimization to achieve the optimal result is within the purview of the skilled artisan.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/S. V. G./
Examiner, Art Unit 1618
11/5/08